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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P37233WO/NCB	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/GB2004/002634	International filing date *(day/month/year)* 18.06.2004	Priority date *(day/month/year)* 19.06.2003
International Patent Classification (IPC) or national classification and IPC G09F3/00		
Applicant REBAN LTD et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.01.2005	23.09.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Pavlov, V Telephone No. +49 89 2399-6067

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/002634

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-20	as originally filed
Claims, Numbers	
1-6	filed with telefax on 09.08.2005
Drawings, Sheets	
1/3-3/3	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/002634

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-6
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

1. Reference is made to the following documents:

D1: GB-A-2 251 608 (BOWES DARBY DESIGN ASSOCIATES LIMITED) 15 July 1992 (1992-07-15)
D2: US 2003/095234 A1 (HEACOCK GREGORY L) 22 May 2003 (2003-05-22)
D3: US-A-5 882 116 (BACKUS ET AL) 16 March 1999 (1999-03-16)
D4: US-A-3 899 295 (HALPERN ET AL) 12 August 1975 (1975-08-12)
D5: US-A-5 228 573 (PAVELLE ET AL) 20 July 1993 (1993-07-20)

2. **Claim 1**: None of the documents cited in the International Search Report discloses a device with features as recited in Claim 1.
Documents D1-D5 disclose different medical devices including tampering markings which become visible directly following exposure of the device to ambient conditions such as light, humidity or air.
The problem to be solved by the present invention is to provide a medical device with marking which is latent and remains latent for a defined and controllable period of time after opening the medical device package.
The solution to this problem consist in that the device is sealed in a gas tight package and it is marked with an oxidisable dye comprising a reducing agent so that the marking becomes visible after a predeterminated period of time.
The advantage is in that the delay period can be adjusted by changing the concentration of the reducing agent. Further the invention represents a relatively simple and effective manner of indicating that the use of the device is no longer valid and would compromise the clinical condition or the safety of the patient.
The claimed device **involves an inventive step** since none of the cited prior art documents, neither alone nor in combination, discloses or fairly suggests a medical device which is sealed in a gas tight package and which is marked with an oxidisable dye comprising a reducing agent so that the marking becomes visible after a predeterminated period of time.
Claim 1 meets therefore the requirements of Article 33(2), 33(3) PCT.

3. **Claims 2-4** are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

4. **Claim 5** relates to the use of a latent marking system which comprises a latent marking according to claim 1 and as such also meet the requirements of the PCT with respect to

novelty and inventive step.

Re Item VII.

1.Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D5 is not mentioned in the description, nor are these documents identified therein.

4. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT. Care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed, Article 34(2)(b) PCT.

5. Claim 5 should refer to the device according to claim 1 in order to meet the requirements of Article 6 PCT taken in combination with Rule 13.1 PCT.

6. Claim 6 contains references to the description and the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

* * *

CLAIMS

1. A medical device sealed in gas tight packaging including a latent marking comprising an oxidisable dye which becomes visible after a predetermined time following exposure of the device to air and further comprising a reducing agent, wherein prior to the opening of the packaging the marking remains invisible and undeveloped and wherein after a period of time from the opening of the packaging the marking becomes visible.

2. A medical device according to claim 1 in which the latent marking is etched into the surface of the device and said marking is obscured by an opaque layer prior to exposure of the device to air, wherein said opaque layer changes to clear or colourless following exposure of the device to air.

3. A medical device according to claim 1 or claim 2 in which the latent marking is carried on a label irremovably adhered to the surface of the device.

4. A medical device according to claim 3 in which the latent marking comprises dyes or chemicals applied in such manner to yield a warning message in the visible spectrum following exposure.

5. The use of a latent marking system which comprises a latent marking comprising an oxidisable dye protected by gas tight packaging in the production of a medical device wherein prior to the opening of the gas tight packaging the latent marking remains invisible and undeveloped and wherein after a period of time from the opening of the packaging the marking becomes visible.

6. A medical device substantially as hereinbefore described with reference to the accompanying drawings.